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UTILITY PATENT APPLICATION TRANSMITTAL

Attorney Docket No.

ROC-17

First Named Inventor or Application Identifier

Mahe, et al.

Express Mail Label No.

EE718927925US

JCS84 U.S. PTO
09/18/96

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Only for new nonprovisional applications under 37 CFR 1.53(b)

APPLICATION ELEMENTS

ADDRESS TO:

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Box Patent Application
Washington, DC 20231

MPEP Chapter 600 concerning utility patent application contents.

1. ☒ Fee Transmittal Form (attached hereto in duplicate)
2. ☒ Specification [Total Pages 15]
(Preferred arrangement set forth below)
 - Descriptive Title of the Invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R&D
 - Reference to Microfiche Appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
3. ☒ Drawing(s) (35 USC 113) [Total Sheets 2]
4. Oath or Declaration
 - a. ☐ Newly executed (original or copy)
 - b. ☒ Unexecuted original
 - c. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional check boxes 5 and 16)
 - i. ☐ Deletion of Inventor(s)
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation by Reference
(useable if Box 4c is checked)
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4c, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ☐ Microfiche Computer Program (Appendix)
7. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 - a. ☐ Computer Readable Copy
 - b. ☐ Paper Copy (identical to computer copy)
 - c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. ☐ Assignment Papers (cover sheet & document(s))
9. ☐ 37 CFR 3.73(b) Statement
(when there is an assignee) ☐ Power of Attorney
10. ☐ English Translation Document (if applicable)
11. ☐ Information Disclosure Statement
(IDS)/PTO-1449 ☐ Copies of IDS Citations
12. ☐ Preliminary Amendment
13. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
14. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)

15. ☐ Other:

16. ☐ If a CONTINUING APPLICATION, check appropriate box and supply the requisite information:
Amend the specification by inserting before the first line: -- This is a ☐ Continuation ☐ Divisional
☐ Continuation-in-Part (CIP) of prior application No.: , filed . --
17. For this divisional application, please cancel original Claims of the prior application before calculating the filing fee.

18. CORRESPONDENCE ADDRESS

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19. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

NAME Andrea L. Colby Reg. No. 30,194

SIGNATURE

Andrea L. Colby

DATE

January 19, 2000

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Applicant: Mahe, Joetzjer, Guise

For : A Cosmetic Composition Based on Menthol and Menthyl
Lactate, Haaving Little Odor and Being Non-
Irritating

Express Mail Certificate

"Express Mail" mailing number: EE718927925US

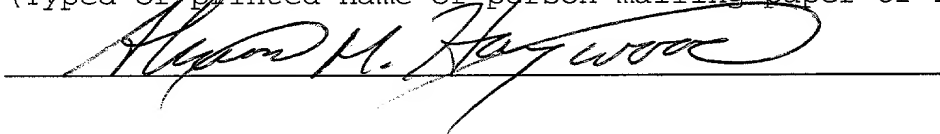
Date of Deposit: January 19, 2000

I hereby certify that this complete application, based on French application 9900704, filed January 22, 1999, including specification pages, claims, and informal drawings, Utility Patent Application Transmittal and unsigned Declaration/Power of Attorney are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

A Combined Declaration and Power of Attorney will be submitted to the United States Patent and Trademark Office upon receipt of the U.S. Serial Number for this patent application.

Alwin M. Haywood

(Typed or printed name of person mailing paper or fee)



A COSMETIC COMPOSITION BASED ON MENTHOL AND MENTHYL LACTATE, HAVING LITTLE ODOR AND BEING NON-IRRITATING

5 The present invention relates to a freshening cosmetic composition characterized in that it comprises 0.01% to 2% by weight menthol and 0.1% to 10% by weight menthyl lactate, the menthol / menthyl lactate ratio lying in the range 1/3 to 1/10, and being such that the odor of the
10 menthol is barely perceptible, said composition possessing the advantage of not being irritating, in particular for the sensitive parts of the human body, while conserving the various beneficial effects of menthol.

15 Menthol is a compound well known to the person skilled in the art for its analgesic, freshening, and odoriferous properties, and it has often been used in cosmetic and pharmaceutical products. In addition, this substance is used as flavoring in numerous preparations for alimentary
20 use or indeed in toothpastes.

As recommended by the Food and Drug Administration (FDA), an effective quantity of menthol in a composition must lie in the range 1.25% to 16%. Nevertheless, at such
25 concentrations, the flavor and the odor of the substance are very powerful, and that is poorly appreciated by consumers. In addition, this power is illustrated by the fact that menthol has been used in industrial methods for manufacturing refrigerant products (FR 74/27045).

30 Concerning cosmetic compositions, there are numerous compounds capable of giving rise to a cooling effect on the skin. For example, patent DE 24 05 900 describes a composition containing menthol, camphor, and alcohol for

preparing a slimming composition designed to induce
metabolization of skin fat by cooling. SU 15 60 215
relates to a composition for treating gingivitis which
contains an association of camphor, menthol, thymol, and
5 salicylic acid. CN 90 10 88 731 relates to a composition
for repelling mosquitos and comprising, in particular,
menthol and camphor.

Compositions specifically based on menthol are described
10 in the documents of the prior art. Nevertheless, given
the overwhelming power of menthol, various esters of
menthol have been prepared for the purpose of reducing the
odoriferous properties of this substance, but most of such
15 esters possess odors that are very disagreeable, making
them unusable in products for local application. In order
to obtain satisfactory effectiveness of their analgesic or
anti-irritant action, said derivatives are required in
quantities that are large. Thus, with an effective
20 quantity of menthol derivatives, said odors constitute a
serious obstacle for use as a cosmetic.

One of said derivatives, menthyl lactate, is used in
pharmaceutical compositions for oral administration for
treating diseases such as respiratory deficiencies, the
25 common cold, sinusitises, bronchitises, or asthma. The
beneficial properties of menthyl lactate are set out, for
example, in WO 97/42945.

Menthyl lactate has also been used in cosmetic
30 compositions for local application as a freshener.
According to the manufacturers, that compound does not
produce the mint odor which characterizes most other
menthol derivatives.

Generally, the compound is at concentrations lying in the range 0.1% to 10% in most cosmetic compositions. For example, WO 96/14840 describes analgesic compositions comprising up to 9% menthyl lactate, and US 5 602 178
5 relates to bath products that have no menthol, containing about 6% menthyl lactate. JP 06329528 and JP 10231238 relate to compositions comprising menthol and menthyl lactate in ratios of 1/1 and 2/1 respectively, however at those ratios, those compositions do not deal with the
10 problems associated with the secondary effects of menthol.

Some of the compositions described in the prior art documents can also contain fragrance reproducing the odor of mint. At low levels, mint odor also contributes to the
15 sensation of cooling provided by menthyl lactate. Nevertheless, some of those fragrances can be expensive, and can give rise to other problems of skin tolerance.

The object of the present invention is thus to provide a
20 freshening composition, in particular a composition for cleaning the body, which is freshening and not irritating, and which also feels pleasant and provides a slight odor of freshness. One of the difficulties thus lies in developing a freshening composition based on menthol and
25 on its derivatives while keeping the mint odor at a level that is sufficiently low. This makes it possible, optionally, to add other freshening fragrances that are less powerful and non-irritating.

30 Thus, no document of the prior art describes or suggests the present invention as defined here-below.

Description

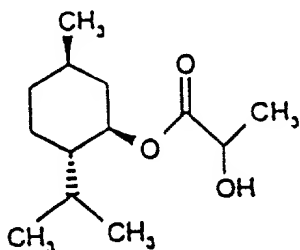
The present invention provides a freshening cosmetic composition characterized in that it comprises 0.01% to 2% by weight menthol and 0.1% to 10% by weight menthyl lactate, the menthol / menthyl lactate ratio lying in the range 1/3 to 1/10, and being such that the odor of the menthol is barely perceptible, said composition not being irritating, in particular for the sensitive parts of the human body. This object is more particularly achieved with a menthol / menthyl lactate ratio lying in the range 1/6 to 1/4. Preferably, the ratio is set at about 1/5, and the composition of the invention comprises 0.1% to 0.5% by weight of menthol, and 0.25% to 1% by weight of menthyl lactate.

Advantageously, the composition comprises 0.08% to 0.12% by weight of menthol and 0.45% to 0.55% of menthyl lactate.

No irritation spoils the beneficial freshening effect obtained by associating menthol and menthyl lactate in the concentrations and ratios specified above.

In addition, the "mint" odor due to the menthol is only faintly perceptible, so the composition can further include at least one fragrance, that can be different from or similar to the fragrance of "mint". In this respect, particular mention can be made of the fragrance "glacier SG 809 A" which reproduces the feeling and the odor of freshness at a concentration of 0.5% to 5% by weight, but without being overpowering and/or irritating.

The general formula of menthyl lactate is as follows:



This compound contains four asymmetrical carbon atoms. It therefore exists in 16 different stereoisomers. In the context of the invention, the term "menthyl lactate" thus covers not only all such stereoisomers, but also any racemate or mixture of said stereoisomers.

The composition of the invention can also comprise at least one surface-active agent selected from anionic surface-active agents, preferably sodium cocoyl isethionate, at a concentration in the range 1% to 10% by weight, at least one thickening agent selected in particular from xantham gums, carbomers, preferably hydroxypropyl methylcellulose at a concentration lying in the range 0.2% to 10% by weight, and at least one conditioning polymer at a concentration lying in the range 0.25% to 2% by weight.

The said composition can also comprise a lustering agent, preferably a mixture of sodium laureth sulfate and of glycol distearate, at a concentration lying in the range 0.1% to 1% by weight, a foaming agent, preferably lauryl betaine, at a concentration lying in the range 1% to 10% by weight, an association of surface active agents such as

betaine, at a concentration lying in the range 1% to 10% by weight, an association of surface active agents such as sodium laureth sulfate, ammonium laureth sulfate, lauryl glucoside, such that the total concentration of surface active agent in the composition lies in the range 5% to 30%, and preferably in the range 15% to 25% by weight, and/or at least one hydrating agent, in particular glycerol and/or polyethylene glycol, at a concentration lying in the range 1% to 20% by weight.

10

Naturally, the composition of the invention is not limited to the ingredients mentioned above. For example, it can also contain a buffer, a dye, an anti-oxidant, and/or a preservative.

15

In a preferred implementation of the present invention, the composition is intended for use as a shower gel. In this case, the composition of the invention may have the following compounds in percentage by weight:

20

- Water	62,92 %
- Sodium laureth sulfate	12 %
- Hydroxypropyl methylcellulose	0,5 %
- Sodium cocoyl isethionate	7 %
25 - Ammonium lauryl sulfate	3 %
- Lauryl glucoside	1 %
- Lauryl betaine	4 %
- Polyquaternium-10	5 %
- Polyethylene glycol (PEG)	2 %
30 - Preservative(s)	0,5 %
- Fragrance	1,5 %
- Menthyl lactate	0,5 %
- Menthol	0,08%

5 The present invention also provides the use of the above-defined composition as a product for washing with, in particular as a two-in-one product for simultaneously cleaning and freshening the skin, in particular as a shower gel or as a foaming gel for the face.

10 **Example 1: freshening shower gel with pH 5.5**

The preferred shower gel of the invention comprises the following compounds in percentage by weight:

	Compounds	% Activity	% by weight	% by weight active
15	- Water		62,92	
	- Sodium laureth sulfate	70	12	8,4
	- Hydroxypropyl methylcellulose	100	0,5	0,5
	- Sodium cocoyl isethionate	100	7	7
	- Ammonium lauryl sulfate	70	3	2,1
20	- Lauryl glucoside	50	1	0,5
	- Lauryl betaine	30	4	1,2
	- Polyquaternium-10	10	5	0,5
	- Polyethylene glycol (PEG)	100	2	2
	- Preservative(s)	100	0,5	0,5
25	- Fagrance	100	1,5	1,5
	- Menthyl lactate	100	0,5	0,5
	- Menthol	100	0,08	0,08

30 **Example 2: comparison of the feeling of freshness**
obtained with various products (refreshing shower gel at pH 5.5)

Table 1: Products tested

Product	Isopulegol	Menthol	Menthyl lactate	"Glacier" fragrance
A	0.5%	0.08%		0.5%
B		0.08%	0.5%	1.0%
C		0.1%	0.25%	1.5%
D		0.08%	0.25%	2%

5 Experimental protocol (blind test):

Products A, B, C, and D were applied to the feet of individuals in a confidential study. 1 ml of each product was spread over the total surface area of a foot, and contact with the product was set at 2 minutes. The product was then rinsed off using warm water, and the feet were dried. The control used in this study consisted in immersing the other foot in water at ambient temperature, and also in water at 4°C for checking the "very cold" parameter. The test was repeated every day for several days.

The refreshing effect of said compositions was evaluated on a linear scale going from 0 (no effect) to 120 (very cold, like ice). This assessment was made immediately after the product had been applied (T0), after the feet had been rinsed and dried (T0'), and then every minute for 5 minutes. In addition to this assessment, an objective evaluation was performed by measuring the temperature of the skin of the feet.

25

The results are given in Tables 2 and 3 below and in Figures 1 and 2 hereafter.

Table 2: Cooling effect compared with control

	T0	T0'	T1	T2	T3	T4	T5
A	33.8	33.3	31.8	28.8	25.3	25.3	22.8
B	24.6	33.5	32.7	34.9	22.5	18.2	20.2
C	31	35.6	24	22.3	15.7	16.5	17.7
D	9.8	16.1	16.4	11	8.6	7.5	3

Table 3: Temperature variation relative to control

	T0	T0'	T1	T2	T3	T4	T5
A	-0.3	-1	-1.2	-1.1	-0.9	-0.7	-0.6
B	-0.02	-0.66	-0.8	-0.9	-0.8	-0.8	-0.7
C	0.16	-0.79	-1.2	-1.2	-1.3	-1.3	-0.9
D	0.25	-0.08	-0.9	-0.9	-0.9	-0.7	-0.7

The result of this study shows that the optimum composition for obtaining the cooling effect corresponds to a menthol / menthyl lactate ratio set at about 1/5, with a menthol content by weight of about 0.08% to 0.1% and a menthyl lactate content by weight of 0.5%.

Example 3: study on how the odor of the composition was assessed

This study set out to determine the optimum ratio between the "mint" scent and the "Glacier" scent in above-described compositions A, B, C, and D. It appears clearly from the assessment of the panel that the "mint" odor, which is very powerful, can give rise to negative feelings above a certain level. This difficulty is eliminated by the menthol / menthyl lactate ratios of the invention, and also by adding the "Glacier" fragrance.

Example 4: in vitro study of eye irritation

Various formulations of the refreshing shower gel type composition having pH 5.5 have been tested to determine potential for irritating the eyes at various concentrations and ratios of menthol and menthyl lactate. The results are given in Table 4 below.

Table 4

Ingredient	Hetcam 5%	Hetcam 1%
Menthol 0.08%	9.0 \pm 2.0 Irritant	6.0 \pm 2.3 Moderately irritant
Menthol 0.08% Menthyl lactate 0.5%	8.0 \pm 0.0 Moderately irritant	4.0 \pm 0.0 Slightly irritant
Menthol 0.1% Menthyl lactate 0.5%	8.0 \pm 0.0 Moderately irritant	4.0 \pm 2.5 Slightly irritant

The combinations menthol 0.08% + menthyl lactate 0.5% and menthol 0.1% + menthyl lactate 0.5% which are effective for refreshing the skin are well tolerated by the most sensitive parts of the body.

Example 5: study concerning skin tolerance

This study was performed to show that the skin tolerates repeated application of the shower gels of the invention. Shower gels as described above, and also baby shampoo used as a reference, were applied to the antero-internal faces of the forearms.

The skin state of the application zone was verified and then humidified lightly using cotton wool moistened with warm water prior to applying the gels by massage that lasted for 10 seconds. A first reading was taken at T = 2
5 minutes. After rinsing in warm water and drying (using absorbant tissue paper), a second reading was performed at T = 10 minutes.

Every day the same application was repeated, and a new reading taken.

10

The results show that no undesirable effect (no burning sensation, no tingling, no itching, no erythema) occurred after using shower gels of the invention.

CLAIMS

1. A freshening cosmetic composition characterized in that it comprises 0.01% to 2% by weight menthol and 0.1% to 10% by weight menthyl lactate, the menthol / menthyl lactate ratio lying in the range 1/3 to 1/10, and being such that the odor of the menthol is barely perceptible, said composition not being irritating, in particular for the sensitive parts of the human body.
2. A composition according to claim 1, characterized in that the menthol / menthyl lactate ratio lies in the range 1/6 to 1/4, and is preferably about 1/5.
3. A composition according to claim 1 or 2, characterized in that it comprises 0.01% to 0.5% by weight of menthol and 0.25% to 1% by weight of menthyl lactate, preferably 0.08% to 0.12% by weight of menthol and 0.45% to 0.55% by weight of menthyl lactate.
4. A composition according to any one of claims 1 to 3, characterized in that it further includes at least one fragrance, in particular the "glacier SG 809 A" fragrance, at a concentration lying in the range 0.5% to 5% by weight.
5. A composition according to any one of claims 1 to 4, characterized in that it further comprises at least one surface active agent selected from anionic surface active agents, preferably sodium cocoyl isethionate, at a concentration lying in the range 1% to 10% by weight.
6. A composition according to claim 5, characterized in that it further comprises at least one thickening agent

selected in particular from xanthan gums, carbomers, preferably hydroxypropyl methylcellulose, at a concentration lying in the range 0.2% to 10% by weight.

- 5 7. A composition according to claim 5 or 6, characterized in that it further comprises at least one conditioning polymer.
- 10 8. A composition according to any one of claims 5 to 7, characterized in that it further comprises a lustering agent, preferably a mixture of sodium laureth sulfate and of glycol distearate, at a concentration lying in the range 0.1% to 1% by weight.
- 15 9. A composition according to any one of claims 5 to 8, characterized in that it further comprises a foaming agent, preferably lauryl betaine, at a concentration lying in the range 1% to 10% by weight.
- 20 10. A composition according to any one of claims 5 to 9, characterized in that it further comprises an association of surface active agents such as sodium laureth sulfate, ammonium laureth sulfate, lauryl glucoside, such that the total concentration in surface active agent in the
- 25 composition lies in the range 5% to 30%, and preferably in the range 15% to 25%, by weight.
- 30 11. A composition according to any one of claims 5 to 10, characterized in that it further comprises at least one hydrating agent, in particular glycerol and/or polyethylene glycol, at a concentration lying in the range 1% to 20% by weight.

12. A composition according to any one of claims 5 to 11, characterized in that it further comprises at least one buffer, a dye, an anti-oxidant, and/or a preservative.

5 13. A composition according to any one of claims 5 to 12, for use as a shower gel.

14. A composition according to any one of claims 5 to 13, characterized in that it comprises the following compounds

10 in percentage by weight:

- Water	62,92 %
- Sodium laureth sulfate	12 %
- Hydroxypropyl methylcellulose	0,5 %
- Sodium cocoyl isethionate	7 %
15 - Ammonium lauryl sulfate	3 %
- Lauryl glucoside	1 %
- Lauryl betaine	4 %
- Polyquaternium-10	5 %
- Polyethylene glycol (PEG)	2 %
20 - Preservative(s)	0,5 %
- Fragrance	1,5 %
- Menthyl lactate	0,5 %
- Menthol	0,08%

15. The use of the composition according to any one of
25 claims 1 to 14, as a bathing product, in particular as a two-in-one product for simultaneously cleansing and freshening the skin.

16. A use according to claim 15 as a shower gel.

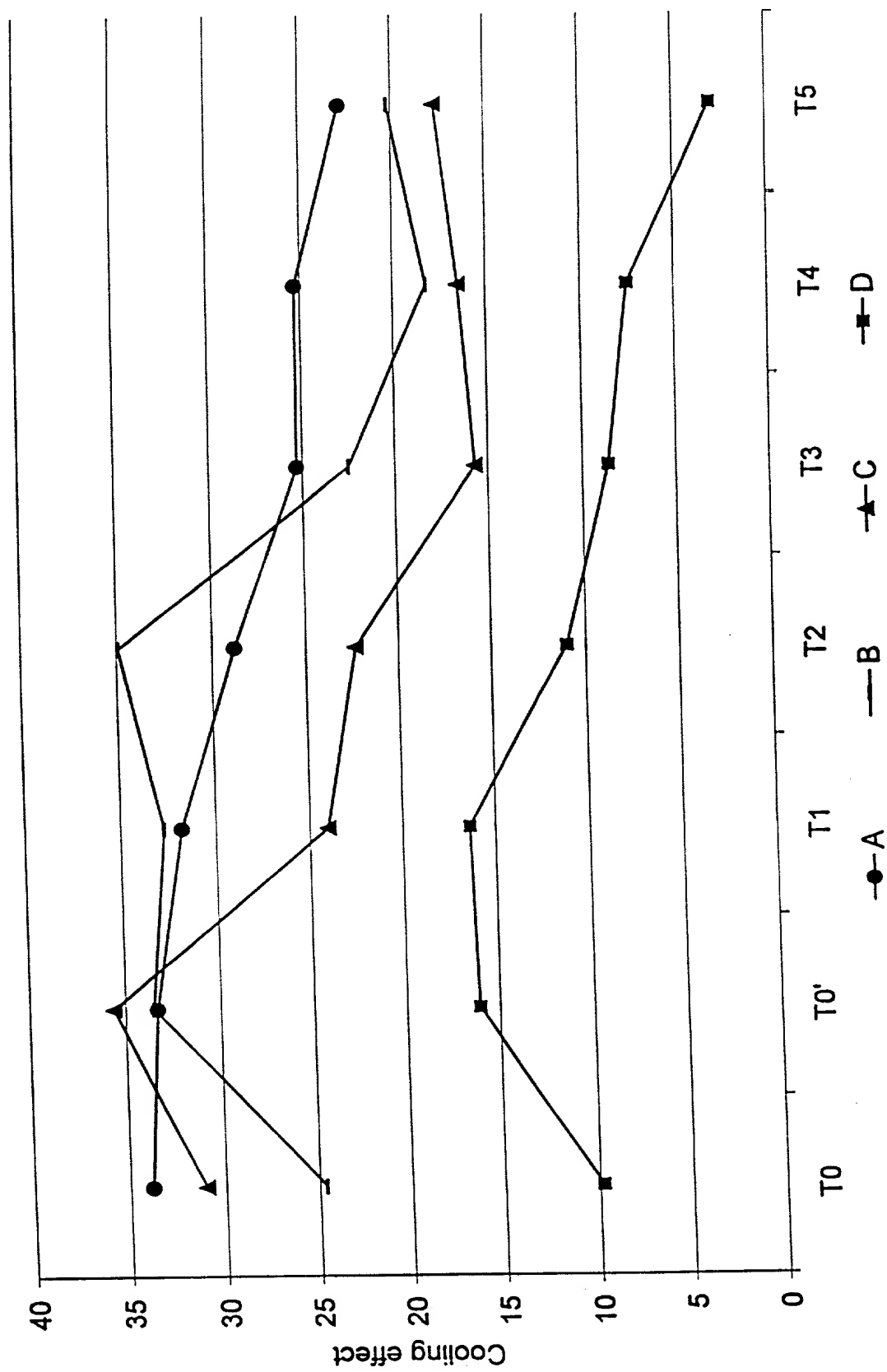
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17. A use according to claim 15 as a foaming gel for the face.

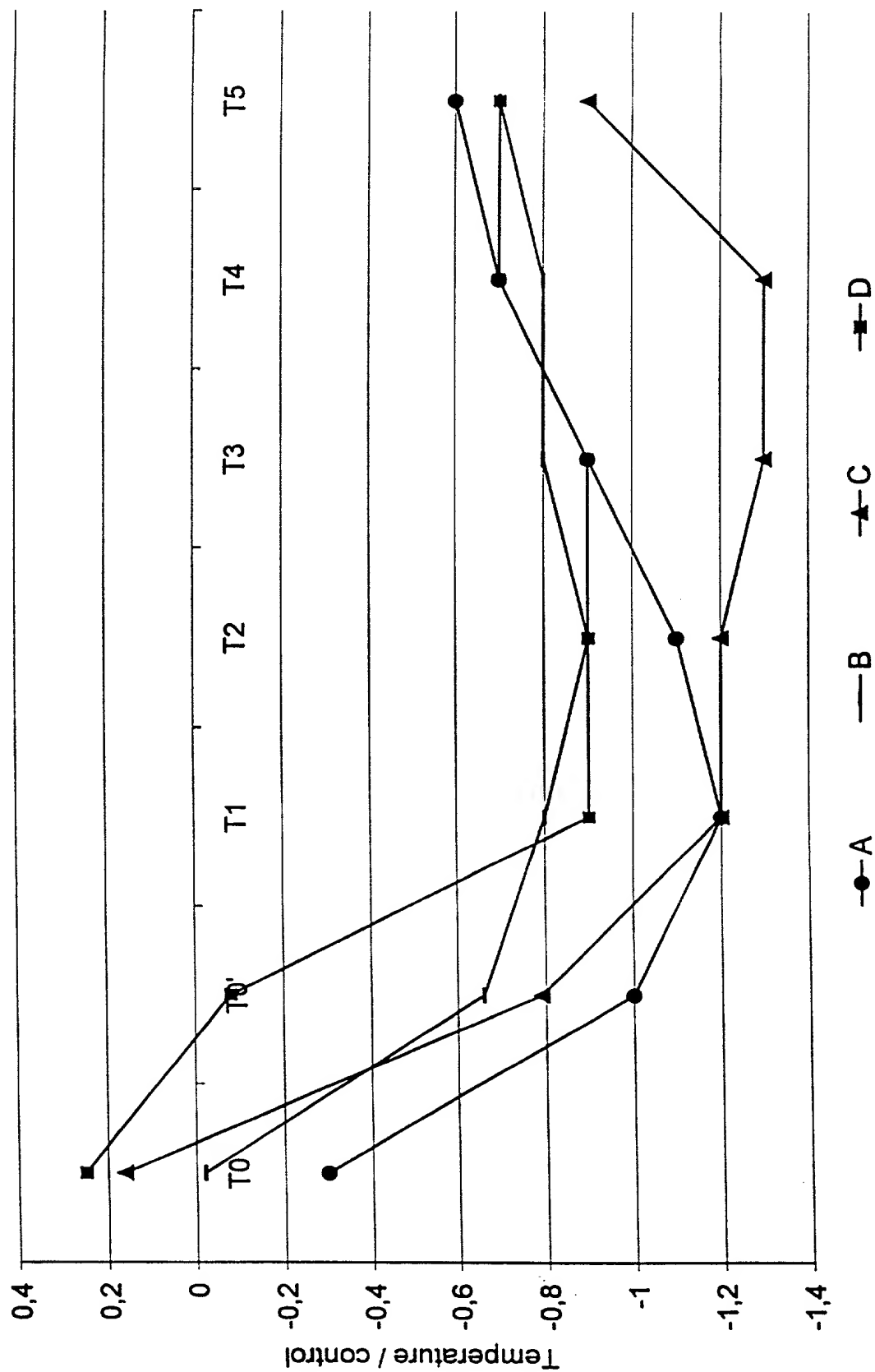
A B S T R A C T

The present invention provides a freshening cosmetic composition characterized in that it comprises 0.01% to 2% by weight menthol and 0.1% to 10% by weight menthyl lactate, the menthol / menthyl lactate ratio lying in the range 1/3 to 1/10, and being such that the odor of the menthol is barely perceptible, said composition not being irritating, in particular for the sensitive parts of the human body, while conserving the various beneficial effects of menthol.

FIGURE I



2/2



DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled A COSMETIC COMPOSITION BASED ON MENTHOL and MENTHYL LACTATE, HAVING LITTLE ODOR AND BEING NON-IRRITATING, the specification of which

(check one) ☒ is attached hereto.

☐ was filed on _____ as

Application Serial No. _____

and was amended on _____.
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 (a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C. 119	
France	9900704	January 22, 1999	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
			<input type="checkbox"/> YES	<input type="checkbox"/> NO
			<input type="checkbox"/> YES	<input type="checkbox"/> NO

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

(Application Number)

(Filing Date)

(Application Number)

(Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.

Filing Date

Status

Application Serial No.

Filing Date

Status

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Audley A. Ciamporzero, Jr. (Reg. #26,051), Steven P. Berman (Reg. #24,772), Andrea L. Colby (Reg. #30,194) and Michael Stark (Reg. #32,495), One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

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I hereby declare that all statements made herein of my own
knowledge are true and that all statements made on information
and belief are believed to be true; and further that these
statements were made with the knowledge that willful false
statements and the like so made are punishable by fine or
imprisonment, or both, under Section 1001 of Title 18 of the
United States Code and that such willful false statements may
jeopardize the validity of the application or any patent issued
thereon.

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Full Name of Sole
or First Inventor

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Full Name of Third Joint
Inventor, If Any

Anne Emmanuelle Guise

Date: _____

Citizenship: France

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(Supply similar information and signature for fourth and
subsequent joint inventors.)